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Attorneys for Plaintiffs
Merck, Sharp & Dohme Corp.,
Bristol-Myers Squibb Company,
and Bristol-Myers Squibb Pharma Co.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK, SHARP & DOHME CORP., BRISTOL-MYERS SQUIBB COMPANY, and BRISTOL-MYERS SQUIBB PHARMA CO.	)	
Plaintiffs,	)	Civil Action No.
v.	)	
HETERO USA INC., and HETERO LABS LIMITED UNIT-III,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck, Sharp & Dohme Corp. ("Merck") and Bristol-Myers Squibb Company and Bristol-Myers Squibb Pharma Co. (collectively, "BMS") by their undersigned attorneys, and for their Complaint against Hetero USA Inc. ("Hetero USA") and Hetero Labs Limited Unit-III ("Hetero Labs") (collectively, "Defendants"), allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 078886, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to market a generic version of BMS's successful Sustiva® tablets that are sold in the United States, including this District.

The Parties

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889-0100.

3. Plaintiff Bristol-Myers Squibb Co. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 345 Park Avenue, New York, NY 10154.

4. Plaintiff Bristol-Myers Squibb Pharma Co., an indirect wholly-owned subsidiary of Bristol-Myers Squibb Co., is a general partnership organized and existing under the laws of the State of Delaware, having its principal place of business at Route 206 and Province Line Road, Lawrenceville, New Jersey 08540.

5. On information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

6. On information and belief, Defendant Hetero Labs is an Indian corporation, having a principal place of business at 22-111, IDA, Jeedimetla, Hyderabad India 500055.

7. On information and belief, Hetero USA is a wholly-owned subsidiary of Hetero Labs.

8. On information and belief, Hetero USA acts as the agent of Hetero Labs Ltd.

9. On information and belief, Defendants collaborate to manufacture, import, distribute, and/or sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the United States generally, and the State of New Jersey specifically.

Jurisdiction and Venue

10. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. On information and belief, this Court has personal jurisdiction over Hetero Labs and Hetero USA.

12. On information and belief, Hetero Labs manufactures bulk pharmaceuticals and pharmaceutical products that are regularly sold and/or used, including sold by Hetero USA, throughout the United States, including this District. Hetero Labs sells its products in the United States, including this District, through retail drug store chains, wholesalers, distributors, health care organizations and governmental concerns.

13. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State. In addition, Defendants sell various products and do business throughout the United States, including specifically in the State of New Jersey.

14. On information and belief, Hetero USA, the United States agent and subsidiary of Hetero Labs, has its principal place of business in New Jersey.

15. Hetero USA's acts and continuous and systematic contact with the State of New Jersey, as an agent of Hetero Labs, are attributable to Hetero Labs for jurisdictional purposes.

16. In the alternative, and to the extent that Defendants are not subject to the jurisdiction of this Court by virtue of Hetero USA's status as a resident of New Jersey, Defendants are subject to the jurisdiction of this Court pursuant to N.J. Ct. R. 4:4-4. Specifically, Defendants regularly do or solicit business, engage in a persistent course of conduct in the State of New Jersey and this District, and/or derive substantial revenue from things used or consumed in the State of New Jersey and this District.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

18. BMS is the holder of New Drug Application ("NDA") No. 21-360 for efavirenz tablets, which BMS markets and sells under the trademark Sustiva®. BMS manufactures and sells a 600 mg dosage strength of Sustiva® tablets in the United States under NDA No. 21-360.

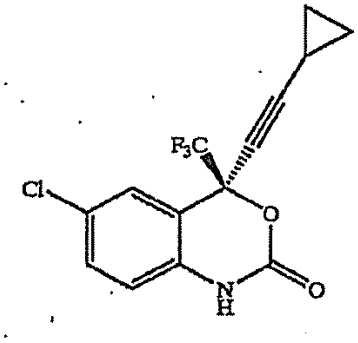
19. United States Patent No. 6,639,071 ("the '071 Patent"), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4-Dihydro-2H-3,1-Benzoxazin-2-One," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 28, 2003. The '071 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("FDA Orange Book") for Sustiva®. A true and correct copy of the '071 Patent is attached as Exhibit A.

20. United States Patent No. 6,939,964 ("the '964 Patent"), entitled "Crystal Forms of (-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4-Dihydro-2H-3,1-Benzoxazin-2-One,"

was duly and legally issued by the USPTO on September 6, 2005. The '964 Patent is also listed in the FDA Orange Book for Sustiva®. A true and correct copy of the '964 Patent is attached as Exhibit B.

21. Merck is the assignee of all rights in the '071 and '964 Patents and has the right to sue for infringement thereof.

22. Efavirenz is a compound that has a molecular formula of $C_{14}H_9ClF_3NO_2$, and has the following chemical structure:



23. Efavirenz can be referred to by any of several chemical names. The chemical name given to efavirenz in the Sustiva® label is "(S)-6-chloro-4-(cyc1opropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one." The chemical name recited for efavirenz in the '071 and '964 Patents is "(-)-6-Chloro-4-Cyclopropylethynyl-4-Trifluoromethyl-1,4-Dihydro-2H-3,1-Benzoxazin-2-One."

24. The named inventors on the '071 and '964 Patents are Louis S. Crocker, Joseph L. Kukura, II, Andrew S. Thompson, Christine Stelmach, and Steven D. Young.

25. Pursuant to an agreement entered into between Merck and the DuPont Merck Pharmaceutical Company ("DPMC"), whereas DPMC interests in the patents were subsequently acquired by BMS, BMS has substantial rights in the '071 and '964 Patents, including but not

limited to, rights associated with being a licensee of the '071 and '964 Patents, and the right to sue for infringement of the '071 and '964 Patents. BMS also derives significant revenue from licensing the '071 and '964 Patents.

DEFENDANTS' INFRINGING ACTIVITY

26. On information and belief, Defendants submitted or caused to be submitted to the FDA an ANDA, specifically ANDA No. 078886, seeking approval to commercially manufacture, use, offer for sale, sell, and import a of 600 mg efavirenz tablets ("Defendants' generic efavirenz product") before the expiration of the '071 and '964 Patents.

27. On information and belief, ANDA No. 078886 seeks FDA approval to manufacture, use, sell, and/or import Defendants' generic efavirenz product for the purpose of treating the HIV-1 infection in combination with other antiretroviral agents.

28. By letter dated October 6, 2015 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 078886 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' generic efavirenz product prior to the expiration date of the '071 and '964 Patents. Defendants' Notice Letter provides a statement of the factual and legal basis for Defendants' paragraph IV certification regarding the '071 and '964 Patents. Defendants' Notice Letter did not provide any statement of the factual and legal basis for any claim of non-infringement of any claim of either the '071 or '964 patents.

29. Defendants' Notice Letter also included an Offer of Confidential Access, pursuant to 21 U.S.C. § 355(j)(5)(C), to certain information from ANDA No. 204411 for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought by BMS and Merck. BMS and Merck did not accepted this

Offer of Confidential Access as Defendants only challenge to the patents was their validity based on the prior art.

COUNT 1
Infringement of U.S. Patent No. 6,639,071

30. Plaintiffs repeat and re-allege paragraphs 1-29 above as if set forth herein.

31. By filing ANDA No. 078886 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' generic efavirenz product prior to the expiration date of the '071 Patent, Defendants have committed an act of infringement of the '071 Patent under 35 U.S.C. § 271(e)(2) and such infringement will cause BMS and Merck irreparable harm unless enjoined by this Court.

32. On information and belief, Defendants lacked a good faith basis for alleging invalidity and thus non-infringement when ANDA No. 078886 was filed and when the Paragraph IV certification was made. Defendants' ANDA is a wholly unjustified infringement of the '071 Patent.

33. On information and belief, the commercial manufacture, use, sale, and/or importation of Defendants' generic efavirenz product by Defendants will infringe, induce infringement, and/or contributorily infringe one or more claims of the '071 Patent literally or under the doctrine of equivalents.

COUNT 2
Infringement of U.S. Patent No. 6,939,964

34. Plaintiffs repeat and re-allege paragraphs 1-29 above as if set forth herein.

35. By filing ANDA No. 078886 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' generic efavirenz product prior to the expiration date of the '964 Patent, Defendants

have committed an act of infringement of the '964 Patent under 35 U.S.C. § 271(e)(2) and such infringement will cause BMS and Merck irreparable harm unless enjoined by this Court.

36. On information and belief, Defendants lacked a good faith basis for alleging invalidity and thus non-infringement when ANDA No. 078886 was filed and when the Paragraph IV certification was made. Defendants' ANDA is a wholly unjustified infringement of the '964 Patent.

37. On information and belief, the commercial manufacture, use, sale, and/or importation of Defendants' generic efavirenz product by Defendants will infringe, induce infringement, and/or contributorily infringe one or more claims of the '964 Patent literally or under the doctrine of equivalents.

COUNT 3
Declaratory Judgment of Patent Infringement of U.S. Patent No. 6,639,071

38. Plaintiffs repeat and re-allege paragraphs 1-29 above as if set forth herein.

39. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps to obtain FDA permission to sell in the United States and, after obtaining FDA permission, to commence the sale in the United States of Defendants' generic efavirenz product before the expiration date of the '071 Patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '071 Patent.

40. The manufacture and/or sale of Defendants' generic efavirenz product by Defendants during the term of the '071 Patent will constitute patent infringement of the '071 Patent under 35 U.S.C. § 271(a) and/or (b).

41. On information and belief, by seeking FDA approval for Defendants' generic efavirenz product as described in ANDA No. 078886, Defendants intend to import into the

United States and/or sell, offer to sell, and/or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Defendants' generic efavirenz product, which would infringe the '071 Patent.

42. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '071 Patent.

COUNT 4
Declaratory Judgment of Patent Infringement of U.S. Patent No. 6,939,964

43. Plaintiffs repeat and re-allege paragraphs 1-29 above as if set forth herein.

44. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps to obtain FDA permission to sell in the United States and, after obtaining FDA permission, to commence the sale in the United States of Defendants' generic efavirenz product prior to the expiration date of the '964 Patent. There is a real and actual controversy between the parties with respect to Defendants' activities and infringement of the '964 Patent.

45. The manufacture and sale of Defendants' generic efavirenz product by Defendants during the term of the '964 Patent will constitute patent infringement of the '964 Patent under 35 U.S.C. § 271(a) and/or (b).

46. On information and belief, by seeking FDA approval for Hetero's generic efavirenz product as described in ANDA No. 078886, Defendants intend to import into the United States and/or sell, offer to sell, and/or use within the United States, all for purposes not exempt under 35 U.S.C. § 271(e)(1), Defendants' generic efavirenz product, which would infringe the '964 Patent.

47. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '964 Patent.

Relief Requested

WHEREFORE, Plaintiffs respectfully pray for the following relief:

(a) A judgment that Defendants have infringed one or more claims of United States Patent No. 6,639,071 by the filing of ANDA No. 078886;

(b) A judgment that Defendants have infringed one or more claims of United States Patent No. 6,939,964 by the filing of ANDA No. 078886;

(c) A judgment ordering that the effective date of any approval of Defendants' ANDA No. 078886 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.§ 355(j)) be a date that is not earlier than the expiration date of United States Patent No. 6,639,071 or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A judgment ordering that the effective date of any approval of Defendants' ANDA No. 078886 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration date of United States Patent No. 6,939,964 or any later date of exclusivity to which Plaintiffs are or become entitled;

(e) A declaration and adjudication that Defendants will infringe United States Patent No. 6,639,071 by their threatened acts of manufacture, importation, sale, offer for sale, and/or use of products covered by said patent prior to expiration date of said patent;

(f) A declaration and adjudication that Defendants will infringe United States Patent No. 6,939,964 by their threatened acts of manufacture, importation, sale, offer for sale, and/or use of products covered by said patent prior to expiration date of said patent;

(g) A permanent injunction enjoining Defendants and their officers, agents, servants, employees, and privies from infringing United States Patent No. 6,639,071;

(h) A permanent injunction enjoining Defendants and their officers, agents, servants, employees, and privies from infringing United States Patent No. 6,939,964;

(i) A judgment that this is an exceptional case and that Plaintiffs are entitled to an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

(j) Costs and expenses in this action; and

(k) Such other relief as this Court may deem just and proper.

November 16, 2015

RESPECTFULLY SUBMITTED,

By: *s/ Gregory J. Bevelock*
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not related to any other pending matter.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on November 16, 2015
Madison, New Jersey

/s Gregory J. Bevelock
Gregory J. Bevelock

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, I hereby certify that the matter in controversy is not subject to compulsory arbitration in that plaintiffs seek, inter alia, injunctive relief.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on November 16, 2015
Madison, New Jersey

/s Gregory J. Bevelock
Gregory J. Bevelock